IN THE UNITED STATES DISTRICT COURT

IN AND FOR THE DISTRICT OF DELAWARE

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THE JOHNS HOPKINS UNIVERSITY, A Maryland Corporation, BAXTER HEALTHCARE CORPORATION, A Delaware Corporation, and BECTON DICKINSON AND COMPANY, a New Jersey Corporation,	:	CIVIL ACTION
Plaintiffs	:	
v.	:	
CELLPRO, A Delaware Corporation,	:	
Defendant	:	NO. 94-105 (RRM)

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Wilmington, Delaware
Wednesday, April 30, 1997
10:30 o'clock, a.m.

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BEFORE: HONORABLE RODERICK R. McKELVIE, U.S.D.C.J.

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PROCEEDINGS

(Proceedings commenced at 10:30 a.m.)

THE COURT: Okay. We're ready to get started.

MR. WARE: May I begin, your Honor?

THE COURT: Sure.

A few final papers slipped through last night that I have not yet read, but you should assume I've read everything.

MR. WARE: We always do, your Honor.

THE COURT: I remember walking past some of them last night.

MR. WARE: We like to think in the middle of the night there's a reason why we're there.

THE COURT: I thought what we'd do is a variation on pick a topic.

MR. WARE: The suggestion that I had was that we begin generally the subject of the injunction, where there are, I think, the most issues to discuss, and that we perhaps address some of the issues separately and both sides be heard on them, and then move on to another point. There are a number of discrete issues.

THE COURT: Actually, I was going to do the opposite.

MR. WARE: You want to hear the whole thing?

THE COURT: No. I thought I'd pick a couple just to talk about where we are with them.

I know that the subject of the injunction is going to be the meat of any argument we have today.

Let's see if we can clear some of the other issues up first.

MR. WARE: All right.

THE COURT: And then come back.

But people won't leave today without getting a chance to walk through all of the issues on the injunction.

But let's talk about -- I guess we've got the marking defense. We've got Beverly documents. We've got misuse.

Why don't we talk about misuse for a minute? Who wants to talk about that defense and where it is?

MR. BLOOMBERG: I'm happy to address that, your Honor.

THE COURT: Good. Okay.

MR. BLOOMBERG: As we indicated in our brief with respect to misuse, in order for judgment to be final, a claim must be fully adjudicated. And while the claims

of the patents here involved have been found to be valid and infringed, nevertheless, there's an issue as to whether or not those claims are unenforceable because of misuse.

Under 35 United States Code 271, Subpart (d), Subpart (5), the statute sets out that misuse or an illegal extension of a patent right by reason of conditioning a license of rights to a patent on the acquisition of rights in another patent where the patent owner has market power in the relevant market is a defense.

And that's the situation here. Almost a textbook example of misuse is contained in Defendant's Exhibit No. 709.

Your Honor will recall that that is a letter dated April 15th, 1992 from Baxter, where they indicated that they were no longer interested in granting a license with a running royalty rate and a lump-sum payment, but wanted from CellPro exclusive rights to CellPro's patents in Europe and Japan and nonexclusive rights in North America.

THE COURT: How do you propose to resolve this issue?

MR. BLOOMBERG: I would propose that discovery be taken on the matter and that it be tried before a jury.

Page 6

THE COURT: Mr. Ware? I've read the briefing on the topic.

MR. WARE: Well, we have not actually briefed the substance of the topic. I think there was brief comment on it in the injunction brief that we filed.

As far as where this is, the patent misuse issue was, in fact, stayed by agreement of the parties, and what we would propose to do, if CellPro is unwilling to withdraw this defense, is we would propose to set a briefing schedule and we will brief it. We think it can very easily be disposed of as a matter of law.

THE COURT: You mean brief a summary judgment?

MR. WARE: Yes. A summary judgment briefing schedule.

THE COURT: The parties agree to defer the presentation of the defense.

Was that in response to my comment that I would otherwise shoot it into outer space, or what does the agreement require?

MR. WARE: The original agreement was, I think -- the original agreement was crafted at the very beginning of the case, probably even before there had been hearings before the Court. And at that time I think that the thinking was probably on the part of

Page 7

both parties that, to the extent that the parties can avoid the unnecessary cost of antitrust-type discovery and proceed with the patents, that they ought to do so.

Moreover, at least at that time, as I recall it, the patent misuse defense was, in substance, a hand-guards-type defense. And so, therefore, if the patents were found to be valid, there would be nothing left of the defense. And that's a further reason that we contend now that there is no justification for going forward with this defense in light of the Court's findings.

But I think that what was contemplated at the time, or at least as the stay was written, the entire patent case was to be resolved and disposed of before dealing with the patent misuse issue, since CellPro has now raised an objection to entry of permanent -- entry of a permanent injunction as part of a final judgment, because technically its patent misuse is pending.

We would like to dispose of the patent misuse defense so that there will be no question about the Court's entry of final judgment, including a permanent injunction.

THE COURT: All right.

MR. WARE: We certainly do not think it would be appropriate to open up antitrust-like discovery on an

Page 8

issue that we truly believe could not survive a Rule 11 motion.

THE COURT: Well, are you in a position -- I mean, do you know what you're moving for summary judgment on?

MR. WARE: Yes.

THE COURT: What the facts are that they'll be relying on?

MR. WARE: Yes. I think that there are several points here that need to be kept in mind.

In the first place, as I understand it, and based upon what Mr. Bloomberg just said, in addition to the hand-guards-type defense, which I assume Mr. Bloomberg would agree, in light of the Court's rulings, doesn't survive as a patent misuse defense, but, in addition, this argument -- the patent-misuse argument seems to be based entirely on an April 15th letter from Baxter to CellPro, which the Court will recall from the trial, in which Baxter simply made a proposal that the license include distribution of CellPro's products in Europe.

And the statement that Mr. Bloomberg just made about conditioning anything on rights under CellPro patents is nowhere contained in that letter and it has never been suggested in five years of litigation until

Page 9

this day that that had anything to do with it.

But, very briefly, we find no legal support for the proposition that a licensee, such as Baxter, cannot ask for distribution as part of a proposal for the -- that is, distribution of the licensed product itself, a product that an infringer could not sell in the United States or could not export under any circumstances.

Secondly, as the Court is aware, this proposal never came to fruition and defenses such as this do not come up when the other party rejects the proposal. And the parties move on in their negotiation.

One does not go back and reconstruct negotiations to find one proposal made on one day that was not accepted and turn that into a patent misuse defense. This is a proposal that never happened.

And, thirdly, as the Court is aware from the trial, on July 15th, 1992, Baxter reiterated its earlier offer of a pure patent license. That is, it said, essentially, We thought you were interested in talking to us about distribution, which is certainly supported by the evidence in this case, but if you're not interested in talking to us about distribution, fine. You can have the license that we offered in the first place.

Page 10

And the law is absolutely clear that, even if there were misuse, that a purging of that misuse takes away the defense entirely.

So what we're talking about is a three-month period in April that was -- certainly, if there was any misuse, was purged by July, when CellPro was given an opportunity on the same terms that were offered before to take a pure patent license. CellPro declined.

There is no patent misuse under those circumstances, and that's a purely legal conclusion that the Court can draw based on undisputed facts.

THE COURT: And what discovery would you want to take?

MR. BLOOMBERG: We would want discovery with respect to the preparation of this April 15th letter. The authorship, the review of the letter, approval of the letter, comments with respect to the letter, documents regarding business plans or financial plans with respect to the countries affected by the conditioning of the license.

As to the issue raised by Mr. Ware regarding this so-called purge letter, which I believe is Defendant's Trial Exhibit No. 637, I think the date is July 22nd, rather than July 15th, 1992.

Your Honor will recall that there was a --

Page 11

shortly thereafter, there was a meeting between Baxter and CellPro representatives, and Mr. Murdock has testified in court that at that meeting the terms of the so-called purge letter were not made available to CellPro, so we would want discovery with respect to that meeting as well.

I think there would also --

THE COURT: It sounds like what Mr. Ware is saying is it's almost a 12(b)(6) motion. And that is you can identify the letter and say that's the basis for your claim. But you can't identify any other facts that would show misuse that would be communications to your client.

In other words, I know you want to go upstream from the letter, but how would that be relevant to establishing a claim if you can't show those matters were communicated to your client?

MR. BLOOMBERG: I think there were actually two communications, your Honor. There was a meeting, I believe, in Southern California at a Baxter facility where the same representations were made orally, and then, as I understand it, from Mr. Murdock's testimony, the substance of that correspondence was confirmed in this letter.

THE COURT: And so wouldn't discovery, at least in the first instance, go to what was communicated to CellPro and what was said in response to that?

Page 12

MR. BLOOMBERG: Yes. To the extent Mr. Ware wants to raise an issue of this purge letter, it seems to me it would be appropriate to find out if those terms were really made available to CellPro. And as I say, Mr. Murdock's testimony is that when CellPro and Baxter met, they were not.

THE COURT: And so when we talk about discovery, I had in mind discovery relating to those communications, as opposed to getting in and rolling around inside Baxter as to these matters. What additional discovery do you need with regard to those two communications?

MR. BLOOMBERG: Beyond what I've already identified?

THE COURT: Right.

MR. BLOOMBERG: The only other issues that I think discovery would bear on this particular misuse would relate to the market power and the relevant market as conditions of 35 United States Code 271(d)(5).

THE COURT: So have you deposed the people who -- the author of the letter, for example?

MR. BLOOMBERG: We have taken his deposition.

THE COURT: Have you deposed people that participated in the meetings?

MR. BLOOMBERG: No, we have not.

Page 13

MR. WARE: Your Honor, just a couple points.

First of all, we would be prepared by the end of next week to file a summary judgment brief and it would be a proper summary judgment type issue that we would argue, and we would like the opportunity to do that rather than permit CellPro to start taking discovery on market power and everything else that you hear about in antitrust cases, which are very time-consuming and expensive.

There is absolutely no law that exists that says someone making a proposal thereby engages in patent misuse.

And I think we ought to have an opportunity to try to have this resolved as a legal matter before going into discovery.

THE COURT: Okay. Let's pick another topic.

Documents relating to Beverly.

MR. BLOOMBERG: This issue, I think, your Honor, relates to dialogue between Dr. Beverly and the plaintiffs with respect to our inequitable-conduct claim.

THE COURT: Okay.

MR. BLOOMBERG: As I understand it, much of these documents have been asserted to be work product or attorney/client, and we don't think it's appropriate to make that claim in connection with a third party.

Page 14

THE COURT: What's the matter in issue? What is it that is still open that these documents are relevant to?

MR. BLOOMBERG: Well, in view of your Honor's ruling on inequitable conduct, I'm not certain that it is -- that it remains a viable issue in the case. But that was the purpose of our seeking those documents --

THE COURT: All right.

MR. BLOOMBERG: - is they bore on inequitable conduct.

THE COURT: All right. Let's move to the topic of motion for – let's move to the three issues together. That is, the motion for injunction, the motion for enhanced damages, and the application for an award of fees.

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Page 15

THE COURT (Continuing): If final judgment is going to be deferred until I can deal with this question of misuse, what happens to your application for an injunction? Do you want a preliminary injunction?

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MR. WARE: I think that, since we're all here, we'd like to argue it, but I think we would like a permanent injunction. And I think it makes more sense, because I think the patent misuse issue can be disposed of quickly. And I don't see what the advantage is, particularly given the stay we've proposed.

There is nothing that can't be addressed in permanent injunction. Insofar as we have proposed that any stay be conditioned on certain payments from CellPro, we've asked that those payments be made based on sales retroactively to March 12 anyway.

So I don't think a brief delay in entering the injunction will affect that. And we have generally accepted the proposition of a stay on the terms proposed, such that, again, I don't think a matter of a couple of weeks or so or a few weeks is going to make much difference.

And I think that we would rather have the -- if this is going to go to the Federal Circuit, we'd rather have them be reviewing a permanent injunction.

Page 16

THE COURT: If I simply enter the order now for the injunction, took the word "permanent" out, just said order for injunction, partial stay of injunction, that would be an appealable order?

MR. WARE: I believe so.

THE COURT: And the case would then go up, presumably go up.

MR. WARE: Yes.

And under 1291(a), I think. And so I think that -- I think it would be helpful to anybody reviewing the record in this case to have the benefit of the Court's further thoughts on some of the issues that are before it now.

THE COURT: See, that's what I was wondering about the relationship of the timing of the injunction and whether or not plaintiffs would prefer to defer the entry of the injunction until I have a chance to write something on the subject of fees and enhanced damages.

And I take it that's what you are saying: Is you would rather wait until I can get something written on that?

MR. WARE: Yes. I think we're perhaps being presumptuous, but we hope that could be in some reasonable time frame. And I do think it would be helpful to the Court of Appeals to have the benefit of the Court's written decision.

Page 17

THE COURT: All right.

MR. WARE: There's a sort of a procedural piece of the attorneys' fee application that we might just discuss briefly –

THE COURT: Sure.

MR. WARE: – because, as we're going through some of these items, to get them out of the way.

I think the issues are pretty straightforward, as far as the Court's authority to award fees. And I think that the issue that we seek some guidance from the Court on has to do with the submissions that the Court wants to see, in terms of the backup information. We have provided to the Court in the application a detailed breakdown by lawyer, by time period of hours. And we have provided the billing rates.

We have not at this time submitted to the Court detailed, daily time reports of lawyers, and we have not submitted to the Court at this time actual hard copies of individual invoices for transcripts and things like that.

We have provided the Court a – subtotals based upon an itemization of the types of different

Page 18

costs that we're seeking. There's no indication in the papers submitted by CellPro that there is objection in concept to the particular types of expenses that we are seeking. And as to the time detail, we have a couple of concerns.

We have the concern that the time detail itself contains information that we regard as confidential work product, and we're reluctant to provide it to opposing counsel, although we are not in the least reluctant to provide it to the Court in camera.

We also had requested some time ago from CellPro the equivalent information from Lyon & Lyon, and that was refused. It seems to us that if Lyon -- if CellPro is proposing to object specifically to the number of hours spent in a time period or whatever, that we would be entitled to see the time spent by their lawyers as well, that that would be at least a relevant piece of evidence.

It seems to us that CellPro -- from reading the opposition brief, that CellPro's objection really is not -- does not have anything to do with the time spent on the case. The only substantive objection was the suggestion that the billing rates ought to be Wilmington billing rates, rather than national billing

Page 19

rates.

CellPro has refused our request that they provide information concerning Lyon and Lyon's billing rates. We think that the billing rates are very much in line with national firms engaged in the sort of practice. But we're a little bit unsure as to what to do at this point. We want to give the Court whatever information it feels it needs to be able to make -- to review the request.

And if that sort of detailed daily report is something that the Court wants to go through over a period of five years, again, we are happy to do it. But we do have this concern about disclosure of all of the details of every potential witness we ever talked to or every issue we looked into or what-have-you.

And there was really a parallel situation earlier in this case, when we sought discovery from Lyon & Lyon with respect to the willfulness issue. And we were not permitted to see any of their internal records, really for the same reason. They were concerned about work product.

And so it seems to us that, in light of that, and in light of CellPro's refusal to provide the information with respect to Lyon and Lyon's time, and in view of the fact also that the fees, we think, that we're

Page 20

requesting are considerably -- they're considerably less than what the plaintiffs actually paid, they are, we believe, considerably less than what CellPro paid to its lawyers, that we really just should not have to make that information available to CellPro.

But that's why we seek guidance.

THE COURT: Do you want to say something?

MR. BLOOMBERG: Well, I think that in order for us to properly evaluate their application, we need to see the supporting documentation, which we have not seen.

As to Mr. Ware's comments regarding our billings, our understanding is that the standard is the local fee rates, as opposed to rates in California.

As to Mr. Ware's comments that, as to the willfulness, we were able to prevent plaintiffs from taking discovery based upon attorney/client and work product.

Your Honor will recall that much of our documentation that was clearly work product or attorney/client was found to be waived and made available to the plaintiffs.

THE COURT: I have a couple thoughts.

My understanding is that at the moment, with the application for fees pending -- and, actually, with my invitation to plaintiffs to file the application,

Page 21

that it's on my plate to resolve before the case goes up.

I'd sort of prefer to find a procedural way to send the case up and do a final review of this issue if and when it comes back affirmed. But if I cannot do that, I cannot do that.

There are a couple of advantages to doing it that way. One advantage to doing it that way is that at that point I think people -- we could have more of an open review of the issue of fees and time put in and comparison, and we could do it in the context -- I don't know whether the Federal Circuit has a separate provision for an award of fees or whether they remand it to the District Court to take care of that issue, but the costs and fees on appeal can then be added in with less concern. And I can even refer to a Master or somebody like that to review it.

If I cannot -- if I cannot put it off, and if plaintiffs don't want me to put it off until the case goes up, then what I'm inclined to do is the following: I can tell you right now I'll apply a national standard to the award for the calculation of fees and costs, as opposed to a local Delaware standard, in part because I don't want to restrain the national Bar with the high Delaware rates that are billed.

Second, what I will do is the following: I'll take the information that the plaintiffs have given me as their best shot. I will review it, to see whether I think it is adequate. If I have any particular questions, I will let people know promptly in time to get information back to me.

CellPro can review what it is that the plaintiffs have submitted and raise specific questions, if they want to, by category, by topic.

But if there is a specific review, I am going to need to look at what is reasonable. And one way of looking at what's reasonable is looking at what CellPro did, in terms of their defense. That is, it was unreasonable to spend eight hours to prepare for that deposition. I'll look and see what the records of Lyon & Lyon show.

So it's going to have to be an issue where, if there's a challenge to the fees, it needs to be identified, either by CellPro or by me in my review.

And I know that there are lots of categories of areas where there's reasonable arguments that this shouldn't be included, this should be included. And I am open to hear argument on it. But if it's going to get into the files, I will find a way to get into the files to get it satisfied or find a way to articulate to

the Appeals Court, to the extent that I award fees, what I did and why I did it.

MR. WARE: Would there be any merit to the idea of addressing, or making a determination about whether fees are to be awarded and under what statutes without actually calculating them and having it go up that way?

THE COURT: That's why God invented lawyers. Judges don't know the answer to anything. They just pick what you say, until Exxon came along, and then I had to come up with my own independent view. I would have thought there are mechanisms to do that. That is, I intend to award.

On the other hand, if, was the Appeals Court, I might say, Look -- well, if you go look at the world about what happens with fee applications, my general sense is that what happens is the case gets tried. Party makes an application for fees. The Trial Court puts it in its pocket. It goes up on appeal. It gets affirmed. If it gets affirmed, it comes back and the Trial Court resolves all of the issues about fees. Our local rule has a specific provision about the time period for filing fee applications, and I thought it was within a certain number of days after the decision came down from the Appeals Court. But why don't you

look at it and see?

MR. WARE: Why don't we look at it and why don't we perhaps communicate back to the Court based on the comments the Court has made what we think makes sense to do at this point.

THE COURT: When you look, you'll find a wonderful opinion by the Third Circuit on the types of attorneys' fees in civil rights cases that says that when you have a civil rights case, and you settle it, and the defendant gives to the -- gets from the plaintiff a general release of all claims, including claims relating to attorneys' fees, that's not a waiver of attorneys' fees under the Civil Rights Law.

MR. WARE: I think I remember that case.

THE COURT: I don't think many people in the Bar know that, but the plaintiffs' bar likes to get a case, get all the money they can, settle, say they waive our claim for fees and then fees for fees under the Civil Rights Law.

Not many Circuit Judges write opinions that bury those type of problems in the law, but we had a few in the Third Circuit that did for a while.

In any event, look at it. See what you want to do. I'm going to leave the bench today and assume that I have on my plate the subject of an application

for fees and costs and the subject of enhanced damages and I'll begin working on it. I'll be applying the standards that I would otherwise apply to it.

To the extent that CellPro raises damages with regard -- awarding fees for appropriateness of certain matters, I looked at the briefing. I didn't notice in the briefing there were many issues that I thought raised particular factual problems, but I'll look. And if CellPro wants to go back and look at it again, that's fine with me. I am interested in getting the right result here.

But I have in the past, and frequently, when a party objects to a rate, I say, fine. So tell me your rate. Then I have some indication of reasonable -- all right. So that's where we are on that.

And I raise all that in part because I thought, one, and I'm sure plaintiffs have thought about this, one way to go would be to simply enter the injunction, and let people go up to the Federal Circuit in the context of a decision that basically says, this implements the jury's decision.

We've got some other issues to take care of here, but there's no reason to delay the case going up. But if the plaintiffs want me to write out on the issue

Page 26

of enhanced damages and the award of attorneys' fees, I'll do that, too. I will assume, unless you apply otherwise --

MR. WARE: That's our present thinking. Yes.

THE COURT: Okay.

On the subject of the terms of the proposed permanent injunction, I have read the briefing. I think I understand the positions of the parties. I think they are pretty clear. I am happy to hear argument, if people want to supplement what they've already said in the briefing. But I don't know that I had any particular questions. I've just got some reading to do, to solve certain questions I've got.

MR. WARE: Let me just ponder that for a minute.

(Pause while Mr. Ware and Mr. Ellis conferred.)

MR. WARE: What we are thinking about, your Honor, would be just highlighting a few of the issues that are maybe most highly contested, and making sure that we have anticipated any questions that the Court might have, and certainly responding to anything further that CellPro has to say on the point.

MR. BLOOMBERG: With your Honor's permission,

Page 27

Mr. Riley would argue the injunction on behalf of CellPro.

THE COURT: Fine.

MR. REILLY: If I may stay here until he's finished, your Honor. I might want to take notes.

THE COURT: Whatever you want.

MR. WARE: Okay. As the Court is aware, the injunction is structured to include essentially four elements, one being a prohibitory injunction, one being a mandatory injunction, the third being a temporary stay, and the fourth, which I guess is part of the temporary stay, relates to calculation of payments of incremental profit during the stay.

I don't think I need to say very much about the prohibitory injunction, other than to emphasize that it is key we believe that there be one. That the end point must be an injunction here. And, in the absence of an injunction, the value of patent rights would be very greatly diminished and would become very difficult for inventors and non-profit institutions, such as Johns Hopkins University, to be able to license out their patents. And there certainly is no exception for infringement that happens to involve medical products. There are injunctions entered all the time against infringing medical devices.

The other aspect of the prohibitory

Page 28

injunction that I might comment on briefly is the proposed two-year injunction with respect to sales in Europe. And there, of course, is a stay of that. But I think that the emphasis really is on a couple of points. One is that this is a remedy for infringement in the United States, and it is really not very different from the very typical sort of trade secret injunction, which typically are worldwide, when somebody has misappropriated a trade secret, and thereby acquired for themselves a head start in a market. And their having done so is very destructive of the marketplace for the licensed patent -- for the patent-holder or the licensee.

And so it is very common to enter that sort of injunction. That's what that's about.

In terms of the mandatory injunction, the repatriation of the 12.8 hybridoma we think is vital.

We have addressed in the papers the conclusion that CellPro clearly did infringe in the United States through its ongoing use of the 12.8 hybridoma after the issuance of the patent.

This is a situation where, by CellPro's attempt to evade the United States patent laws by sending hybridoma cells to Canada in the midst of litigation, the patent-holders have been deprived of

Page 29

rights that they would otherwise have had.

They would have had the right, upon a finding of infringement, to request destruction of the infringing hybridoma, in which case it could not have been sent to Canada.

They could have requested, and the Court would properly have entered an injunction against exporting the infringing hybridoma.

So they were deprived of those rights. And to remedy that, the Court must require them to bring it back to the United States.

It's really no different than a party that sends out or smuggles out of the United States stolen goods. They are still within the possession and control -- not possession, but control of the infringer, and they ought to be brought back.

We even know, by reason of the filings that have been made most recently, that CellPro itself recognized that the operation in Canada was really a sham and that, as soon as the jury verdict came down in the first trial, CellPro ceased manufacturing abroad. They had no real intention of manufacturing there.

The mandatory injunction also includes a destruction order. I think, ultimately, the plaintiffs are entitled to it.

Page 30

The plaintiffs should not be in a position where they have to police all of the activities of CellPro regarding 12.8. It is very easy to clone hybridoma cells and ship them out of the United States. We shouldn't have to be guarding that. We shouldn't have to learn that at some point in the future that, all of a sudden, people are being supplied with 12.8 antibody from the Cayman Islands or somewhere else.

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Page 31

MR. WARE (Continuing): And so we think that that's an appropriate order ultimately.

However, in view of the stay that we seek, that will not come to pass in the near term.

What I might suggest, because I think there are enough differences here that -- I might suggest that we hear from Mr. Reilly on those aspects of the injunction before turning to the stay, because otherwise, I will have kind of a long presentation here.

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Page 32

THE COURT: What's the evidentiary record on the shipping of the 12.8 hybridoma to Canada?

MR. WARE: There had been summary judgment briefing in 1985 on the issue, and there was deposition testimony of a Mr. Bordinaro from CellPro that had been submitted to the Court at the time and Mr. Bordinaro, in fact, submitted a declaration.

There are certain facts that are undisputed, including the fact that it was in 1993 that CellPro shipped the hybridoma to Canada. And the various facts on which we -- the various facts we have pointed to in terms of CellPro's maintenance and use of the 12.8 antibody in the United States after the patent issued and before the cells were shipped to Canada are also undisputed. That is, they come out of Mr. Bordinaro's deposition.

So that's really the basis of the evidentiary record, then.

Mr. Bordinaro acknowledged that the -- that although CellPro first cloned the cells that they obtained from the Fred Hutchinson Cancer Research Institute in -- I believe it's early 1990, that the cell bank that they made out of those cells was not even released for use until -- I believe it was in '91

Page 33

or '92. Maybe even in '93, but sometime after the patent issued, because there's a whole series of steps of quality-control testing and things that have to be done before you can release it.

But, again, it's based on the evidence -- that -- both documentary and deposition testimony of Mr. Bordinaro.

THE COURT: All right.

MR. REILLY: Good morning, your Honor.

THE COURT: Good morning.

MR. REILLY: Let me start with the injunctions, request for repatriation of hybridoma in Canada. This was summary judgment briefed in 1995. I think what happened is the trial crept up on us and it was never argued. It's briefed a lot more thoroughly in 1995. I would refer the Court to DI-158, 159, 249 and 269 was the briefing on that.

We have a rather different interpretation of Mr. Bordinaro's testimony. The facts, as I understand them, is that -- and this much is certainly undisputed -- the 12.8 antibody was discovered before the '204 patent issued.

There were six vials shipped to Canada. The six vials shipped to Canada were frozen. They remained in a frozen state, unaltered and undealt

Page 34

with, except to keep them cold so they would not die, until a time in 1993, when they were sent to Canada.

Simply put, CellPro's position is that the hybridoma is not an infringing product because, even if it is within the claims of the patent, the patent didn't issue until subsequently.

It's sort of like the parable of the widgets, if I may say, your Honor. If you make a bushel basket full of widgets and you have them there and then one subsequent day I get a patents issued to me that reads on the widgets, they do not become infringing widgets. We know that because Section 271(a) tells us that. He who makes, uses or sells during the -- in the United States during the term of the patent infringes and not otherwise.

So a device or a product that is made before a patent issued does not become an infringing product if the patent issues.

If you thereafter use it or sell it, those are acts of infringements.

But, certainly, you would be perfectly within your legal rights to store your widgets for 17 years or until I fail to pay my maintenance fee or something or my patent is declared invalid.

Simply storing a product that was made

Page 35

before a patent issued does not turn that product into something that infringes. The mere act of keeping it around, and the mere act of shipping it out of the country, are not acts of infringement. And we do cite law on that.

If you didn't want to keep your widgets in the United States for 17 years until my patent expired, you could ship them to Canada. And if I had no patent rights in Canada, you could just sell them in Canada, and that would not be an act of infringement.

And, again, what tells us that is 271(a), which says that he who, within the term of the patent in the United States, makes, uses or sells, infringes the patent.

The case that plaintiffs have cited for the point that mere storage constitutes an infringing act is what I call the howitzer case. It's the Olson case. Very strange case. And I think it's sui generis. It dealt with howitzers. And the Court says the use of howitzers in peacetime is to just sit around and be a deterrent, so their storage is use.

The other distinguishing fact about that case is the howitzers were made during the term of the patent. The 12.8 antibody was discovered before the patent issued. So the mere fact of shipping the

Page 36

hybridoma to Canada, the mere fact of storing it in its frozen state before it went to Canada cannot be acts of infringement.

There's no act of infringement that has been committed with respect to those six frozen vials in Canada. They were thawed out after and used in Canada, but not in the United States. It's simply our position there has been no act of infringement with respect to those vials. Plaintiffs have called this an evasion of the U.S. patent laws, but it's no more of an evasion than if I moved to Switzerland and lawfully pay my taxes in Switzerland. Once I move out of the country and don't have any activities here that tax is due on, it's certainly not an evasion of the U.S. tax laws.

So I think plaintiffs' position just basically violates the principle of territoriality of the patent laws and there's no basis to repatriate that hybridoma.

The other thing I should mention is that CellPro does not really own it free and clear. The hybridoma is licensed from the Fred Hutchinson Cancer Center and there's provision in the license agreement that if the -- the license ever terminates, CellPro would have to return any of the remaining stock of the hybridoma to the Fred Hutchinson Cancer Center.

Page 37

The other point I would make, your Honor, is that to actually round up the hybridoma and kill it would be as one clinician said to me when I mentioned this, it would be like killing Einstein.

This is not the situation where someone makes a bunch of Rolex watch knock-offs and they call a press conference and hire a steam roller and flatten the watches.

A hybridoma, as your Honor well knows, is a unique, living organism. You can never get another one like it as a practical matter. And if it were ordered destroyed then, as a practical matter, neither CellPro nor anyone else could begin using it again when the patent expires or is ultimately found invalid or for any other reason becomes unenforceable.

Something made before a patent begins, there ought to at least be a right to store it until the patent term is over. And I think that the law should be clear on that, and that to actually order this hybridoma destroyed really would be a great loss to science and way, way beyond the bounds of, I think, anything that the Court should fairly do, even if there were an act of infringement here, which there hasn't been.

THE COURT: During the discovery, was there discovery of documents about the motive that CellPro had

Page 38

and communications that related to the decision to ship the hybridoma to Canada?

MR. WARE: Well, there was discovery of communications from Lyon & Lyon to CellPro. This was a scheme that was devised by CellPro and its lawyers, and CellPro --

THE COURT: Were these documents withheld as privileged?

MR. WARE: They were produced.

THE COURT: They were produced?

MR. WARE: Yes.

THE COURT: And they are in the summary judgment briefing?

MR. WARE: I don't think so. I don't think so.

I don't know -- well, no, I don't think so.

THE COURT: Can you provide them?

MR. WARE: Yes. We can provide them.

THE COURT: To the extent there are documents that may shed some lights on CellPro's intent at the time, I'd be interested in seeing them.

MR. WARE: Yes. Now, there was no discovery, that is whether we deposed Mr. Bloomberg, for example, I don't think we went into those. But those documents themselves do exist.

Page 39

I do want to emphasize that, as Mr. Reilly said, CellPro is a licensee from the Fred Hutchinson. Nobody is talking about destroying the Fred Hutchinson's 12.8 hybridoma. These are simply cells that were cloned off of the hybridoma at Fred Hutchinson.

And our point is simply that CellPro should not be permitted to continue to be in possession of hybridoma cells, because it is just very easy to ship them out of the country.

So -- but we are not talking about killing some living thing that can never be reproduced, because that's exactly the point of all of the cells in the freezer at Fred Hutchinson. You can simply clone more off of them.

I think also that what Mr. Riley is missing in his discussion of widgets is that these aren't widgets, and what you do with a hybridoma is you store it and you test it from time to time so as to be able to replenish your stock.

And so that is the use. Putting hybridoma into service is basically putting it into the freezer and pulling cells out from time to time and doing quality-control testing. So it's a very different situation from widgets.

And there's an interesting case that is

Page 40

cited in our reply brief. It's called Amgen versus Ellenex (phonetic) that actually does involve frozen cell lines, oddly enough, in Bothel (phonetic), Washington, a different company. The decision was written by Judge Dimmick, who was the original Judge in the declaratory action brought in Washington.

And so one thing we do know if this case had not left Washington and if that's where it was in 1993, that Judge Dimmick's view would have been that the very maintenance of the cell line that is described by CellPro is, in fact, an infringing use.

And so, had we stayed in Washington, I'm sure that Judge Dimmick would have been quite prepared to enjoin the shipment of those cells out of the Washington.

What is also different about this is that the notion that's presented here is that these are just a bunch of different vials, and that the particular vial that they sent to Canada itself wasn't thawed and tested.

But a hybridoma is a hybridoma. And that's how a hybridoma is stored. It's stored in a bunch of vials. And so you cannot simply say that every time you pull one off, that you are -- that that had nothing to do with the 12.8 hybridoma.

When you do quality-control testing of the

Page 41

hybridoma, you're testing cells in a particular vial, because the results of that test tell you something about all of the cells. And so you can't just say there are billions of cells, and so we only tested these cells and we sent these cells. I mean, the patent covers a hybridoma, and that's what a hybridoma is. It's a whole lot of cells that have been cloned that are all identical that are sitting in the freezer in vials. So...

MR. REILLY: Your Honor, the patent -- what right is secured by a patent is what we need to focus on. The patent doesn't really cover a hybridoma. The patent covers the right to exclude others from making, using and selling the hybridoma in the United States during the term of the patent. That is exactly what the patent covers, or is what it has been ruled to cover by the Court.

And, again, the fact that this hybridoma was made before the patent issued and that the particular six vials that were shipped to Canada just remained in the frozen state since before the patent issued until 1993, when they were shipped up to Canada, they simply were not used in the United States.

As for your Honor's question about what CellPro's motive is in shipping them to Canada, I would

Page 42

first suggest to your Honor that that is irrelevant. The only thing relevant is that Canada is not the United States and 271(a) says that you've got to be in the United States to infringe.

Beyond that, your Honor, there is --

THE COURT: It sounds like a good business opportunity, if somebody could rent a hospital ship and become some kind of a freezer bank, stay off the coast. We hold it while you litigate?

MR. WARE: We hold, you litigate.

MR. REILLY: They don't have to hold it. They can use it to their heart's content in any country but the United States is my point.

THE COURT: A lot of Caribbean countries. It's too hot down there. That's why you picked Canada.

MR. REILLY: There is some evidence that we recently submitted on CellPro's intent.

On the question of -- of intent, we did submit a declaration of Dr. Tarnowski (phonetic) with CellPro, who reports that the hybridoma, after it got to Canada, was thawed out and was used to make biotinylated 12.8 antibody, which was not sold into the U.S., I believe, but it was sold in Europe.

So the biotinylated 12.8 was made from the hybridoma in Canada for sale in Europe which, again,

Page 43

is lawful, given the territorial scope of the United States patent.

The next point that Mr. Ware --

THE COURT: You could call that ship Patent Pending.

MR. REILLY: You could.

THE COURT: Go ahead. I'm sorry.

MR. REILLY: The next point that Mr. Ware raised, your Honor, was about the two-year prohibitory injunction in Europe.

As we read that proposal, it would forbid CellPro from making any stem cell antibody product in Europe, even if the antibody was 12.8 that had never even been in the United States during the term of the patent, or even if it had been some other antibody. And the idea is a head-start injunction.

I think it's -- let me get to my notes for a moment.

(Pause.)

MR. REILLY: I think it's telling, your Honor, that there are no patent cases that are cited in support of this notion that you can have a head-start injunction as a remedy for past patent infringement.

The remedy for past patent infringement is the remedy that the plaintiffs have already had in

Page 44

this case. They have had a jury award them damages based on their sales in Europe.

The section of the patent statute that deals with injunctions speaks of the injunction as being a remedy to prevent infringement.

Selling a stem cell antibody, making a stem cell antibody product in Europe, where the plaintiffs have no patent coverage and concede that they can't now get any, is not an infringement of the U.S. patent law.

And if the court were to enter an injunction granting that relief, the Court would really be giving them a remedy that they have already had a damages remedy for. The whole idea of a reasonable royalty damage claim is to compensate the plaintiffs for past sales.

We are now talking really about future conduct. And I think that the -- the injunction can't really enjoin something that's not an act of infringement.

And to take an antibody that is wholly developed in Europe, or to taken 12.8 antibody that has never been in the United States during the term of this patent, simply would not be an infringement of the U.S. patent laws.

The other point on that, your Honor -- and we've briefed this -- is the whole question of international comity and the extraterritorial effects

Page 45

of patent laws, we have a declaration we filed from Mr. Colin Overbury, who is a high official of the European Commission, that talks about the effect that extraterritorial enforcement of U.S. patent laws would have on the important antitrust and competition policies of the European union. And he opines that this is something that would implicate the comity issues and it could provoke international retaliation.

The other thing I would say, to go on about these trade secret cases, is that they really, really are distinguishable, when you consider the difference between what a trade secret is and what a patent is.

Trade secrets are creatures of state law. The cases are cases the plaintiff cites, where the Court is sitting in diversity and applying state law. Trade secrets aren't necessarily territorial in scope. You can come in and steal somebody's trade secret and you're still a thief. If you come into the United States and see somebody's patented device in operation, you are free to take it with you and use it anywhere where he does not have patent coverage.

I would say, too, that the -- there's an international network of cooperating patent laws that really finds no counterpart in trade secret law. Trade secret law is basically a state common-law thing

Page 46

that recently has been -- relatively recently has been codified in some states.

Whereas you look in the patent laws, and the U.S. patent laws are carefully tailored to intermesh with international patent laws. There are -- wherein all countries respect the territoriality of each other's patent laws and expect that they will not apply extraterritorially.

And to render -- issue an injunction in a patent case that has extraterritorial effects that would say to CellPro, Even though your activities in Europe do not infringe any U.S. patent and can't, because they're beyond the territorial scope of that patent, still we are enjoining you for patent law reasons.

That would be an extraterritorial enforcement in a situation where you've got a rather complex international scheme of rights, all countries -- each country understands that its own patent laws are territorial. And the way the European union would be if these plaintiffs wanted patent protection in Europe to prevent their business competitors from selling a stem cell antibody product in Europe, they should have gotten patent production here.

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Page 47

MR. REILLY (Continuing): They did not fill the requirement to get patent protection in Europe, so they have not got it. So free competition is what should obtain.

Trade secrets are worldwide. And trade secret is a potentially -- I should not say infinite, but indefinite duration. As long as it remains a secret, it is entitled to trade secret protection.

By the same token, if you reverse-engineer a trade secret -- if you make something that tastes just like Coca-Cola without cracking the safe and getting the Coca-Cola formula, then you are perfectly legal to do that.

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Page 48

MR. REILLY (Continuing): So there are extremely large and significant differences between the nature and scope of the right that patent confers and the right that trade secret protection confers.

The right that trade secret protection confers is simply a right to prevent people from, you know, invading your secret and igniting it. The right that patents confers is a right to exclude others for a limited term in a limited place that in this case does not include Europe.

So, for all these reasons, we think that the trade secret cases are totally inapt. There's a good reason why they cite trade secret cases and not patent cases. And there are serious issues of international comity that would be implicated if that kind of an injunction were issued.

MR. WARE: I think I have about three or four very quick comments.

First, on the trade secret cases, it's actually interesting. Trade secret law is a creature of state -- of the states, not federal, and those trade secrets are, in many cases, not even recognized in many foreign countries, and yet certainly courts in the United States feel perfectly able to enter orders like

Page 49

this and would certainly similarly feel comfortable entering an order against a United States company that steals trade secrets in the United States and ships products out, or ships confidential work papers or scientific technical papers out.

They could be ordered to bring them back even if they had shipped them to -- I was going to say China, which maybe does not recognize them, or even if they've got them on that offshore tender someplace.

THE COURT: Even if they take them to Spain and Germany and they used to work for Ford Motor Company.

MR. WARE: These things do happen from time to time.

And the United States courts do exercise their authority to provide remedies that are meaningful remedies for past violations.

And the Federal Circuit has made clear on a number of occasions that it is perfectly within the authority of a District Court to enter injunctions that not only prevent future infringement, but that remedy past infringement, that will have an impact in the future if not remedied.

And that's what's going on here. There have been injunctions entered even in medical cases where an

Page 50

infringer has been ordered to destroy clinical data that was generated through infringement. That's the Pfizer case. And the data itself is not infringing, but it's a remedy that was granted.

And we are not asking for that particular remedy, but we are asking for remedy for conduct in the United States that unfairly impacts the future development of Baxter's business in Europe as a result of the head start.

So I guess I'd move on now to the stay of the injunction.

MR. REILLY: If I may just respond to that very briefly, your Honor...

THE COURT: Yes.

MR. REILLY: Again, for past infringement, they've already had their remedy. They've now gotten the verdict for damages on a reasonable royalty theory.

The other point to keep in mind about this head start injunction in Europe is that the logic of such an injunction I think has not really been supported in the proof. Plaintiffs assert in their briefs that, but for infringement in the United States, we would never have gotten going in Europe.

It's nowhere been proved on this record that that is true. And, in fact, Dr. Tarnowski's

Page 51

recently-filed declaration demonstrates that CellPro could have, and did, for a while, manufacture the biotinylated antibody in Europe.

And the reason why he stopped was that we won the trial in 1995.

And so the logic kind of breaks down that, but for this infringement, we never would have gotten a head start in Europe. We could have manufactured outside the United States, and that's perfectly proper and encouraged by the laws of other countries.

So I think the basic premise is -- really isn't there, whereas, again, in a trade secret case, it is there, because, by definition, when you steal a trade secret and exploit the trade secret, you're getting some kind of a head start from the trade secret that you couldn't have gotten without the trade secret. CellPro could have gotten the same head start by manufacturing outside the United States, which they would have if they had thought there was any reason to do it. And, indeed, they did for a while.

MR. WARE: Yes. The interesting thing about this argument is that CellPro has never actually told us in opposing this injunction what they actually plan to do, as far as foreign manufacturing and sales.

I believe what's going on is actually that

Page 52

they are doing the manufacturing in the United States, in Bothel, Washington, and that what we're actually talking about is an injunction that will have -- will, in the end, amount only to enjoining them from exporting goods from the United States.

There's no evidence that they have any other plans anyway. So in terms of the impact of this injunction, it may be only United States activities anyway.

MR. REILLY: Well, your Honor, I would invite Mr. Ware to withdraw that part of his proposal that would call for an injunction in Europe. That's why we have this issue.

MR. WARE: But if you are manufacturing in the United States, you can't even raise this point.

MR. REILLY: All right. I think my problem, your Honor, is that the injunction, the proposed injunction, as written, would forbid CellPro for two years from making any stem cell antibody product in Europe, regardless of where they got the antibody. And if they didn't get it in the United States during the term of the patent, it simply does not infringe.

And what CellPro may do later, I mean, certainly, it is a business option for any company that is blocked under U.S. patent law to manufacture where

Page 53

its business competitor has not seen fit to get himself patent protection, such as in Europe.

I can't represent to the court that CellPro right now, today, is starting manufacturing operations in Europe. They may be. They may not be. I just don't know the answer to that question. But they certainly ought to be welcome to do it. And the plaintiffs are proposing a form of injunction that would prohibit them to do it, even though it wouldn't be an infringing act if they did do it. That's my problem.

THE COURT: All right.

MR. WARE: If we can move on to the stay...

THE COURT: All right.

MR. WARE: I think that, analytically, it helps to sort of subdivide the stay into several areas. One is United States versus the rest of the world and what we have proposed is different in the United States from in the rest of the world.

And the second is subdivision between CellPro's commercial sales of its device for the rather limited FDA approval, approved indication that it has versus the clinical trials.

And then within the clinical trials, there's really a subdivision as between clinical trials

Page 54

that are ongoing and have been approved by the FDA, and the applicable IRB, and clinical trials that simply might be proposed at some point in the future.

I think, as to commercial sales in the United States, there's not a whole lot that needs to be said, except to come back in a few minutes to the issue of the incremental profit payment on those sales. But I don't think there's any serious objection to the scope of the stay and the terms of the stay with respect to commercial sales.

The thrust of CellPro's objections relates to clinical trials. And as we have made clear in the papers that we have filed, it was never the plaintiffs' intention to preclude CellPro from continuing to supply those clinicians who are engaged in FDA-approved clinical trials.

We do believe, however, that there is no reason why CellPro should be able to conduct clinical trials indefinitely, that is to start new clinical trials, because in that realm, there are two products available to a clinician, neither of which currently has FDA approval with respect to the particular uses in the clinical trials.

If CellPro had FDA approval, they couldn't be doing clinical trials. And so CellPro's device is

Page 55

every bit as much experimental in that particular indication as is Baxter's.

And the concern here is that these are -- this is a situation where CellPro, if permitted to continue forever doing these clinical trials with the SC device, could make it extremely difficult for Baxter to ever establish a market for a commercial market, because I'm sure clinicians are quite content to continue to receive supplies for free or at a very reduced cost. And these are situations where there's absolutely no reason why the clinician cannot specify the Baxter Isolex device in a future trial.

So we are not proposing that they must substitute the device in a current trial. But -- so we think it's appropriate to draw that distinction. And I think that, really, in terms of the public interest, if anything, it is more disruptive, if you're looking down the road to the future to a trial that hasn't even been proposed to the FDA yet, that it is really even more disruptive for the clinicians themselves and the hospitals themselves to embark upon clinical trials using a product that ultimately will be enjoined from use.

And so, therefore, just as Judge Farnan indicated in the Critikon case, it can be actually

Page 56

more disruptive to permit an infringer providing infringing products.

The arguments presented by CellPro in its filing last week are principally -- principally amount to disparagement of Baxter's product.

And we have filed a motion to strike those declarations. We do not think that it is proper for the Court to consider ex-parte declarations filed post-trial. Those deponents have never -- declarants have never been deposed or cross-examined. They were not identified in the pretrial order. The facts on which they rely were not identified in the pretrial order. And as the Shyley (phonetic) case indicates, in a case involving Lyon & Lyon itself, this is not a proper way to decide the scope of an injunction.

We have, nevertheless, submitted on behalf of the plaintiffs some declarations on very short notice, which I think makes clear that the Baxter device is a -- is an entirely acceptable device that clinicians, in fact, use. It's installed in more than 40 cites around the United States and Canada, at some of the most prestigious institutions, hospitals and other institutions. Clinicians are very satisfied with it. It works well.

In fact, it has comparisons -- in

Page 57

comparisons with CellPro's device, it has been shown to work, to provide better results and to be every bit as easy to use, if not more so.

So the Court certainly should not deal with this issue of a stay based upon the assumptions that the plaintiffs or a licensed party under the patents has nothing to offer that will address the medical need.

So what we have tried to do is we have tried to craft a stay that will assure that there is no patient who will be deprived of access to the inventions that Dr. Civin made at Johns Hopkins University. But this needs to be a transition period. It cannot go on forever.

I anticipate from CellPro's papers that the argument is now being asserted that as to the clinical trials, that somehow the injunction can't cover them because of Section 271(e). And I remind the Court that, at the last hearing we had on March 13th, counsel for plaintiff stood up and acknowledged that there was no Section 271(e) in the -- defense in the case. It was not raised by CellPro in the answer. It was not raised in the pretrial order.

CellPro would have had to prove that the particular supplies of products to institutions engaged in clinical trials were actually exempt under Section

Page 58

271(e). That's a burden that they did not undertake. And, therefore, they cannot now complain that an injunction will encompass sales or supply of products that somehow they might have proven to be exempt under Section 271(e).

In fact, as we indicated in our papers, we do not think that they could have made that -- met that burden of proof in any event, because that exemption is a very narrow one that relates to uses that are solely -- solely for developing FDA information, and CellPro certainly could not say when it makes the 12.8 antibody that it is doing so solely for purposes of FDA reporting requirements, because it has a commercial device. The commercial device is on sale in the United States and in Europe.

But, in any event, that issue simply is not before the Court and it is a red herring.

I think that it might make sense to stop now. I have some comments on the incremental profit and I have a few more comments -- although I think we pretty much covered the European sales issues. But I think I will stop right now.

THE COURT: Okay.

MR. REILLY: Your Honor, if I may respond to that, I think what counsel was alluding to for part of

Page 59

the time was the paper we recently received wherein the plaintiffs have moved to strike our declarations that deal with issues, including the 271(e)(1) issue.

As to the late service point, Mr. Ware didn't get into it, and perhaps neither should I, but I understand that the Fed Ex people failed to come and pick up the declarations and get them to Boston on the night when they were left for Fed Ex to get them.

Local counsel received them timely. Counsel in Boston received them a day late. And to the extent that there's any innuendo in the brief that this was deliberate, I understand that Mr. Powers, our local counsel, is prepared to explain how this all happened, if the Court wants to hear about it.

As for the point about 271(e)(1) not being in the pretrial order, it was in the pretrial order, and the plaintiffs themselves put it there.

If one goes to plaintiffs' statement of issue of law No. 9, which is found under Pages 9 -- at Pages 9 and 10 under Tab 3 of the pretrial order, they frame the injunction issue thus:

Quote, "Whether plaintiffs are entitled to an injunction prohibiting CellPro" -- "CellPro from importing, exporting, making, using, offering for

Page 60

sale or selling the SEPRATE SC except for use in clinical trials meeting the requirements of the exception stated in," and then they cite 271(e)(1) and 271(e)(3).

So it certainly was in the issues that were stated.

As to whether the parties were expected to put in all their proof relevant to the injunction at the trial, I would remind the Court of a couple of things. The plaintiff successfully moved for an order in limine, which forbade CellPro to do anything that would intimate to the jury that there even might be an injunction in this case.

So we couldn't very well put in all our proof relevant to the injunction issue at the trial in light of the motion in limine.

Furthermore, the injunction, proposed form of injunction, was something we never saw until after the trial, and all kinds of issues that it raises, such as what would be the public health impacts, the impacts on CellPro to have this $2,000 per unit price, to have a prospective two-year injunction in Europe, and a host of other issues that pop out at you when you read the proposed injunction, but not before, couldn't possibly

Page 61

have been fairly expected to have been addressed at trial.

And I think the last time the Court really went on record as to what it expected to be done about the injunction and how it saw this issue being handled was at a hearing. Before the last trial -- I have a February 21st, 1995 transcript and at Page 29 of that, Lines 2 through 14, the Court said, and again I'm quoting:

"Here's what I think I will do. I am generally familiar with the case law that talks about situations where a Court may not grant an injunction because of the public interest in having health care products on the market. I think what I will do is simply defer the discovery on that. If we get a jury verdict, and the plaintiffs pop up and say, Judge, enter an injunction today, we can then have a discussion about what further information CellPro may want in order to oppose the entry of an injunction at that point. We may know at that point where the FDA is on these products."

And your Honor goes on with other comments

Page 62

along those lines.
I think it's pretty clear from that -- and we certainly understood -- that the court contemplated some separate determination preceded by discovery of some kind on the exact form and scope that any injunction might take. That's a fair way to handle it. That's how we thought it would happen. That is how we expected it to happen.
And, indeed, it is really the only way that it can happen, given the order in limine that prevented any kind of meaningful ventilation of the injunction issues during the jury trial.
And when we weren't yet on notice of the proposed injunction, the details of the proposed injunction they would seek. And a lot of very important objections go to those details.
So that answers their motion to strike the declarations. I think the declarations are fairly in the case.
Now, if I may move on to the substance of it, counsel calls the 271(e)(1) issue a red herring. It is not, for several reasons. The most fundamental of them is the 271(e)(1), when you read it together with 271(e)(3), imposes an explicit limitation on judicial power. (e)(3) says no injunction, or other relief,

Page 63

may be granted which would prohibit the making, using, selling or offering to sell in the United States a patented invention solely for reasons related to FDA approval.
It's kind of a rare thing, I think, in federal statutes where you have one section saying the Court can issue injunctions and then you have a separate and more specific section saying the injunction may not forbid this.
So it's -- patent rights are creatures of statute and the remedies that can be granted are limited by statute. And in this case Congress has determined that it simply is not an act of infringement to use someone's patented technology for purposes of getting your FDA approvals ready.
For that reason, it would, I think, be -- it would be violative of 271(e)(3) if the Court were to enter the injunction in the form that plaintiffs request, because as long as something is a bona fide FDA study that is aimed at either what is called a label expansion, to get an approval to sell the device and advertise it for another use, another indication, or a new device approval -- and CellPro, as we point out in our declarations, has some second-generation devices that would combine the use of the 12.8 antibody to

Page 64

enrich the stem cells with the use of other antibody to enrich or deplete for other kinds of cells. And those are being FDA tested right now.
And under 271(e)(1), CellPro has a perfect right prospectively to do that.
To counsel's point that we somehow waived the right to rely on 271(e) by not asserting it as a damage defense, I think that view misapprehends the difference between prospective remedies and retrospective remedies.
Damages is a retrospective remedy. That's for what you've already done. And from the fact that CellPro chose not to argue that a portion of its past sales were FDA exempt should in no way foreclose CellPro from arguing that if, in the future, it wants to do things that are FDA exempt, it can.
The prospective aspect of this has nothing to do with the retrospective aspect of it. On the face of their own statement of issues of law, the plaintiffs acknowledge that 271(e) is the immovable object here. An injunction that does not make allowance for 271(e) exempt uses is an injunction that is on its face overbroad and I think unlawful.
I just don't think that the Court could sign it in the form in which plaintiffs propose it without running afoul of two 71.

Page 65

Now, just what is a 271(e)(1) exempt use is something that can be debated later. But an injunction that says you can't make any uses that -- that says you may make uses that are 271(e)(1) exempt is certainly, I think, what it would have to say. The injunction would have to carve out that exception if an injunction were entered at all.
And the fact that CellPro has a commercial product I don't think is sufficient as a matter of law to support a conclusion that there can be no conceivable use of that product that would be exempt.
We have in approximately 20 of our clinicians' declarations and also in the declaration of Dr. Cindy Jacobs, who's CellPro's Director of Clinical Research, we talk about a number of studies that are going on, 50 or 60, I think, in the United States alone at this point, and in some Europe that are under IDE's and are for the purpose of gathering data to either do a label expansion or to get a new device approval.
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Page 66

MR. REILLY (Continuing): Those are not commercial sales. They can be made at a commercial price. There is an FDA regulation and it is Mr. David Weed's declaration that gets into this. He is the person who is the former Deputy Counsel, I think, of the FDA. He explains that when you supply medical devices in support of a clinical trial, you can sell them at retail. You can at most charge only a cost recovery price.

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Page 67

MR. REILLY (Continuing): And as Dr. Jacobs' declaration explains, some of the doctors expect reduced-priced goods or they won't participate in trials and some of the patients can't afford it unless the devices are supplied cheaper or free.

Now, I think Mr. Ware has basically conceded that point. I see that his revised form of injunction, at least for present clinical trials, that is once already under way, would exempt from this $2,000 per unit sold royalty rate any CellPro disposables that are supplied in connection with these FDA trials.

I think that is correct, and that's how it has to be. I think anything else would run afoul of 271(e)(1).

So the main point, your Honor, is that a large amount of the uses of the CellPro device that are going on presently are in support of -- either CellPro-sponsored or investigator-sponsored investigational device exempt uses that have been cleared with the FDA, and these are uses being made for the purpose of either getting a label expansion or getting a new device approval, and it's exactly what 271(e)(1) permits.

There's absolutely no basis in law or in logic

Page 68

to drawing the line at present -- presently under way trials. Under the law, it simply is not an act of infringement, and it cannot be enjoined if a company uses the patented technology to seek FDA approvals.

This was debated in Congress and the plaintiffs' side lost on that question. It's simply exempt and you can't read it out of the law. It is a limitation on judicial power.

One more point that I wanted to make on that. Just on the point of why the injunction will be overbroad on its face if it failed to make allowance for 271(e)(1) exempt activities, there are a number of things that CellPro would have to do to support its FDA trials, whether it was making a commercial product in the United States or not.

And, as I understand the injunction, it would prevent CellPro, at least after Baxter got an FDA or some licensee got an FDA approval, from even using the CellPro device for its one approved application, which is bone marrow transplantation for breast cancer.

If that use were enjoined, then just about everything else that CellPro would be doing would be in support of some kind of an IDE.

As for the notion that CellPro could somehow go hog wild and just do some unlimited number of clinical

Page 69

trials for some bad-faith reason, I think the best answer to that is that's a problem for the FDA; it's not a problem for this Court.

And the FDA has ways to deal with that. Again, I would refer the Court to Mr. Wida's declaration, which I think makes the point, and Dr. Jacobs' does also: That the FDA does not let you use clinical trials just to get out there and do commercial distribution. They won't let you charge a commercial price. They won't let you test market. They won't let you advertise the product for that use. And they want to know that it's real science that you are doing, and they want to see your protocol.

And once you have your IDE, you'd better not depart from the protocol. You'd better treat only the patients who say you'll treat and only the way you'll say you'll treat them, and you'd better also comply with all the reporting and data-gathering requirements, because the purpose of an IDE is not to be some kind of a blind for commercial sales.

And, in fact, the FDA can, and does, revoke IDE permissions if it sees someone is using them as a blind for commercialization. I think that's something the FDA can police and this Court does not have to.

MR. WARE: It seems like this is a good

Page 70

moment to jump in.
MR. REILLY: I think it is.
THE COURT: All right.
MR. WARE: Okay. Well, several comments.
First, as a sort of procedural posture, I think at the time the statement in the pretrial order that counsel referred to was done, I think that plaintiffs thought that perhaps it was CellPro's intention to raise this. But they did not. They made it clear they were not.
They even provided, with respect to damages, they provided a statement of all of the revenue received from SC – the SC device, which quite explicitly included the cost of recovery sales as well, and did not assert a 271(e) defense.
Mr. Reilly suggested that, while there's a big difference between damages and a future injunction, but what they actually did was they did not assert the defense as to liability either. And that statement is actually made in a brief that was filed in this court on March 13th, 1997. And we cite it in our brief.
They stated, We have not asserted a 271(e) defense to liability or damages.
If you are going to take the position that particular sales and uses of your product are

Page 71

noninfringing by reason of 271(e), you would be asserting a defense to liability. That defense was not asserted, so that – so that all of the types of trials that are going on now were treated by CellPro as no different from the commercial sales, and there simply is no basis, legal or factual, in the circumstances to then take the position that, well, all those sales are noninfringing under 271(e) and, therefore, the Court can't enter an injunction.
The approach that Mr. Reilly is suggesting is one that the Federal Circuit has said is improper. In the Eli Lilly V. Medtronic case, or one of the Eli Lilly versus Medtronic cases, which we cite in our brief, the Court said that you don't just – you don't enter an injunction that says that it's subject to whatever 271(e) exemption there might be. That is an issue – that's a liability issue. And so that the defendant has to actually prove that particular sales are sales that are noninfringing under 271(e).
So if that does not happen, they get enjoined. Those sales have been found to be infringing sales.
There was no exception in the Court's determination that CellPro was infringing for any particular types of sales. They are all infringing and

Page 72

they should all be subject to the injunction.
It is also not enough to simply recite the phrase clinical trial and say that they're exempt. There is a serious factual issue about the 271(e) exemption because of the use of the phrase "solely" in the statute, which would be read out of it entirely under Mr. Reilly's argument.
So that there are real issues that would have to actually have been presented and tried to – for CellPro to establish that certain types of sales were noninfringing and protected under Section 271(e).
The suggestion that certain sales or uses of the device must be for 271(e) purposes, because they're being used in clinical trials, overlooks the fact that that isn't the point – or that's certainly not the first point, when CellPro has infringed. CellPro has infringed the '204 patent when it has made the 12.8 antibody. And when it makes the 12.8 antibody, it certainly cannot say that its infringement at is solely for seeking FDA approval.
But that defense is not in the case and it certainly was never contemplated in the pretrial order and it certainly was never discussed with this Court before the trial in March that we were then going to have another trial after the completion of that trial at which

Page 7

there would then be testimony and evidence presented in order to establish a 271(e) defense that would go to the scope of the injunction. That was never discussed, never contemplated. And CellPro made its choice when it decided not to raise a 271(e) defense.
I think it recognized that it would have a very difficult time establishing a 271(e) defense, and it did not choose to do that.
THE COURT: Why? Why would it have a difficult time?
MR. WARE: Because of the "solely" language in the statute. It is – there is only an exemption where the infringement that is done is infringement solely for purposes of meeting FDA requirements. And that simply is not the case here, because they have – they make the 12.8 antibody for all kinds of purposes and uses which have nothing to do with FDA approval; i.e., selling the product commercially in the United States and in Europe.
So – but, in any event, it's a question of fact. It's one that has to be determined as a liability question. And if a party does not raise it, they are not entitled to come in afterwards and raise it. And they are not entitled, then, to – when an injunction is entered, to then say, Well, now, every

Page 74

time that we're accused of violating the injunction, we have to come in and have a factual determination of whether or not that particular activity was infringing because of 271(e).

That's exactly what the Federal Circuit said they did not want to have happen and that issues that go to liability of whether a party is infringing or is exempt from infringement under 271(e), that's supposed to be tried as part of liability. And if a party waives that defense, it is not in the case.

As far as the future trials, too, the other thing I wanted to suggest is -- I mean, the point of -- to the extent that there -- let me back up.

The point of the statute was to -- to allow a certain -- certain activities sort of in the period before the patent expired. We're talking about a patent that expires ten years from now. And clinical trials that CellPro might start at this time are certainly not ones that are designed to put it in a position to offer a product when the patent expires.

And there is a serious disruption and harm to Baxter by permitting CellPro, in effect, to just indefinitely engage in clinical trials.

And so that's why we're talking about an injunction that the -- the injunction on its face would

Page 75

cover all of these activities. We're then talking about the scope of the stay from that injunction. And we do not think that the Court is required, or should enter such a broad stay as to really eliminate for the next ten years any serious effect of the permanent injunction.

So that's a different -- that's the difference there.

One other thing I wanted to say, I was pleased to hear actually Mr. Reilly's comment about the limitations on the approved use of the CellPro product and his acknowledgment that offering that product for uses other than the limited approved use that he referred to is improper.

A considerable amount of time was -- considerable amount of space in CellPro's declarations that it filed and in its opposing brief were devoted to the argument that, because CellPro had an approved product, that somehow that made it much more appropriate than the Baxter product, even for uses that were not the approved uses.

And that argument runs directly into the FDA's very strict limitation on what an approved use is. And anything other than what the FDA has authorized as the approved use is an experimental use as to which no decision has been made by the FDA as to whether it is

Page 76

safe and effective for that use. It's still experimental.

And so, as we pointed out in our papers, for those clinical trials, the Baxter product and the CellPro product are both in the same boat.

Something came across my desk yesterday that I would like to bring to the Court's attention, because it relates to this very argument that CellPro made, that its own FDA approval gives it some special availability to clinicians. And this is a letter that I was unaware of until yesterday that was written to CellPro by the FDA earlier this year that is highly critical of CellPro's actions in promoting its product to doctors for other than its approved use.

And it actually told CellPro that what it was doing was misbranding the product, that it was making misrepresentations about the product, that it was making statements that are regarded by the FDA to be false and misleading.

And I would like to submit that to the Court (handing document to the court).

THE COURT: Do you want to identify the date and author?

MR. WARE: Yes.

MR. REILLY: Your Honor, I would object to it,

Page 77

first for lack of notice, and, secondly, as irrelevant to any question that's before the Court.

(Mr. Ware handed document to Mr. Reilly.)

MR. WARE: Just for the record, this is a letter -- I can't read the date. It appears to be January something, 1987. And just so there's no mystery about where --

THE COURT: '97?

MR. WARE: 1997. January 1997 from the FDA to Monica Krieger of CellPro. She is the chief regulatory person. This letter was sent to Baxter's Law Department anonymously from someone at CellPro who evidently believed that the conduct of CellPro in this regard was, indeed, inappropriate. And I just learned of this letter yesterday.

But I think that that should be in the record because I think that the record presents a very misleading argument with respect to the -- the availability of the CellPro device to be used for so-called off-label purposes. That appears in several of the declarations, including Mr. Wida's declaration, I believe.

And so from the FDA's perspective, that's not the case. It's not appropriate. And so any such use needs to be under an authorized IDE, just as does

Page 78

currently any use of the Baxter device.

And so that's -- that's why, I think, that it is important, as we look down the road towards future clinical trials, to recognize that these are two products, either one of which can be specified by a clinician for a clinical trial, and that there is -- there is no public health concern of the nature raised by CellPro with respect to its current clinical trials when we are focusing on the future.

So I think what I would -- I think it would make sense to turn to a few comments about the incremental profit calculation.

MR. REILLY: If I may just respond to some of these points briefly...

This letter, your Honor, as I understand it, CellPro put around a Christmas card. They had on it a drawing by some little child whose life had been saved by the CellPro device. And there was a little biographical blurb about the kid on the back of the Christmas card that said what the child had been successfully treated for. And it was off-label use. And the FDA felt that that was inappropriate.

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Page 79

MR. REILLY (Continuing): As I understand it, just because I think the record is in a very confusing state about this.

Off-label use is something that the FDA does not control. Advertising of a medical product in interstate commerce for an off-label use is something that the FDA controls. The FDA does not, however, regulate the practice of medicine.

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Page 80

MR. REILLY (Continuing): And once a device is FDA-approved for one indication, it may be sold in interstate commerce.

Once it is sold in interstate commerce, any physician within the bounds of state law and professional ethics may make the judgment that it ought to be used to treat a certain patient in a certain way, as long as it's not advertised for that use, as long as the doctor doesn't basically proceed on other than an one-by-one medical judgment basis. Off-label uses are permitted.

And I would refer the Court to the declaration of Mr. Wida, the former Deputy Counsel of the FDA. Paragraph 7, specifically, talks about off-label uses. And it says, off-label uses are allowed. And they're quite common. The difference is if you have an unapproved device that's not approved for any indication, it may not move in interstate commerce for the treatment of human patients at all, except as part of a clinical trial.

So that physicians are relatively free to -- for humanitarian reasons, make an off-label use of an FDA-approved device on a particular patient in particular circumstances. The FDA does not disapprove

Page 81

that. They would disapprove it if he advertised that he was doing that.

But that's where it goes. And I mean that's where it stops. And so there is a significant advantage to having a device that's FDA-approved from one indication. And, in fact, we have among our declarations Dr. Wida's -- Mr. Wida's declaration explains at great length why it is that the idea that Baxter, with just a patchwork quilt of IDE's and no FDA approval for any indication, cannot fill the gap in patient care availability.

That would happen if the CellPro device were frozen at the number of columns that CellPro had in use as of March 12, which is what their injunction proposes. That March 12 date is a scant three months after CellPro got its FDA approval.

I think there is something like 50 or 60 sites in the United States that have CellPro devices right now. And there are a lot more cancer patients and a lot more places than that.

So this business about off-label use and whether Baxter and CellPro are in the same boat, other than for the indicated use, I think is an important thing to dwell on for a moment, because it is just absolutely infeasible that Baxter, without an FDA approval, could

Page 82

completely satisfy the needs of patients for treatment.
There are very, very significant constraints on the ability of physicians to make choices in patient treatment when they've got only an unapproved device to work with.
Several of our declarants make the point that off-label use is a big -- a big advantage. Ease of recruitment of patients is an advantage of having a -- an FDA-approved device.
Ease of getting insurance reimbursement without which some patients couldn't be treated is -- is something that's mentioned by Dr. Anderson and also by Dr. Sender in his declaration, and also by Mr. Wida.
The ease of getting new IDE's approved, if your device has already been found safe and effective for one application, is quite significant. I think eight or nine of our clinician declarants have remarked on the fact that it's easier to get IDE's approved in your institutional review board and your hospital, university, and also by the FDA, if you can say this has been found safe and effective by the FDA for at least this one application.
So the point of all this, and I think Mr. Ware has gotten -- fairly gotten into it by this letter -- the point of it is that you just can't -- it

Page 83

is unrealistic to think, it is totally impractical to think, that if CellPro remained frozen at the number of devices and places in the United States as of March 12th, that Baxter, with no FDA approval, could go in there and completely fill the market.
It can't. It cannot sell its device commercially. It cannot advertise its device. And IDE's are not -- they are not a stopgap for commercial sales. I think Mr. Wida's declaration makes that very, very clear. There would be a shortfall in filling the needs of patients for care if -- if CellPro were frozen at the number of devices it's now got in place.
MR. WARE: There's just a couple of brief points.
CellPro actually provided us no data at all about the number of sites they were in. And I think that it is entirely conjecture on the part of Mr. Reilly's part that those sites cannot somehow fill the needs for patient care.
Bone marrow transplants aren't performed in every little local hospital. They are performed in transplant centers. And it's not clear to me that there are even are a whole lot more transplant centers in the United States, which is one reason I think there was essentially no comment on this issue in CellPro's

Page 84

briefing. I don't think that's a real issue, as far as the commercial sales.
And as far as everything else that CellPro is talking about, they are talking about their own uses of their product under IDE's, not under approved usage -- uses, and in areas where the -- the FDA has not concluded that CellPro's device is safe and effective for use.
So I think we're just, you know, we're talking about IDE situations that -- I mean, that's what we're talking about when we're talking about the stay. This off-label use is -- I think our point is this is not something -- this is not a basis on which the Court should tailor the stay of the injunction in order to specially encourage off-label use of CellPro's product, because it's something that, while the FDA may not have the authority to regulate on individual doctors' use of it, it certainly does disapprove of it, and that's not a good basis for an injunction or a stay of an injunction, to encourage that.
THE COURT: Stop just for a minute. I need to take a break or stop.
How much longer do you think you'll be?
MR. WARE: Very short. I think, really, the last thing that I wanted to address very shortly was

Page 85

just the incremental profit point.
THE COURT: All right. Why don't we talk about that real quick, then I'm going to need to go.
MR. WARE: Okay.
THE COURT: If anybody has to say anything they want to say, feel free to write me.
MR. WARE: I think, first of all, just conceptually, it's important to underscore our point here, which is that anything other than payment to the plaintiffs of incremental profit allows CellPro to benefit from its willful infringement, and we don't think that should be permitted.
So I think what the -- so I think the concept is entirely appropriate, and I have not really heard much argument from CellPro as to why it isn't.
What we're mostly arguing about here is the floor that we proposed simply to avoid all of the kinds of -- all of the kinds of accounting games that can be played once you give somebody the ability to calculate their incremental profit.
And I am sure CellPro would, if we had no floor at all, it's quite clear from Mr. Simpson's affidavit, that they would say we lose money on every sale but I guess hope to make it up with the volume.
And I think beyond that, what I'd like to

Page 86

do is -- do you want very briefly -- there are just a couple -- there are a few things that we just picked up that are I think just worth mentioning, although if the Court prefer that we do it by letter, we can. But they have to do with the calculations that Mr. Simpson did. And I think we can show the Court why those calculations are so off base that they should not be considered at all as a basis for establishing a floor for this -- for this incremental profit calculation.

But if the Court would prefer that we do that in writing, we can do that.

THE COURT: Realistically, what will happen is I will go back and reread the transcript of what was said, when I've got Simpson in mind and exactly what went on with it. It may be just as easy for you to read the letter. I've got another argument coming up at 2:00 that I need to get focused on.

So if you don't mind, I'm happy to have you write a supplemental paper, if you don't mind. I'd just as soon get it done that way, if that's all right.

MR. WARE: Yes.

THE COURT: I saw you all carrying a disk around. I take it that's probably a disk of the order of the form of injunction?

MR. WARE: Would that be helpful?

Page 87

THE COURT: There's no harm in passing it up.

MR. BLOOMBERG: I have two very brief points, your Honor, one with respect to misuse.

THE COURT: Sure.

MR. BLOOMBERG: Will we be allowed to take discovery on that topic, your Honor?

THE COURT: I think what I am going to do is have plaintiffs file their motion for summary judgment, stay discovery on it, and then during the briefing, if you can identify for me what facts you believe you would obtain during discovery as you would under Rule 56, in any event. And then we'll see where we are.

MR. BLOOMBERG: Fine.

And the last point, once we see the letter that they are submitting with respect to Mr. Simpson, may we file some response if we think it's appropriate?

MR. ELLIS: Your Honor, I don't think that's quite fair, because they elected to file Mr. Simpson's declaration without disclosing the documents from which Mr. Simpson extrapolated his data.

Mr. Simpson's declaration is arrangement of figures that are taken from what is described as unaudited financial statements of CellPro that have not been provided to us. And based on undisclosed hearsay

Page 88

conversations with Mr. Culver, who is the CFO of -- the CFO of CellPro.

Now, if we, so to speak, criticize the Simpson declaration, which it is very -- incidentally, very easy to do, then they will come back. They'll play around with the figures again. We still won't have the figures that they are relying on.

The only point we are trying to make, your Honor, is -- in that letter -- and it's already addressed in part in Dr. Hausman's declaration, which had to be prepared. We only got their papers last week. Is that the figures are not trustworthy because they are very selective.

For example, they are loading an entire year's worth of manufacturing costs and selling costs into a year when they only had partial revenues in the U.S.. They're comparing apples and oranges.

They're also loading the entire costs of making all 12.8 profits, including the big devices themselves, on to the cost of the disposable units. But these are issues we can point out. Simply to say the Court shouldn't rely on them, but I don't think they should now be offered an opportunity, so to speak, to fix what Mr. Simpson has done while still depriving us of the information on which he is relying.

Page 89

THE COURT: All right.

MR. REILLY: Your Honor, I think what probably would be appropriate would be some discovery on the question of whether the injunction -- and if it were not stayed, would bust CellPro. I think the issue is actually broader than that.

There was nothing stealth or sneaky about Mr. Simpson's declaration. The reason why it had to be put together on such short notice is that this $2,000 per unit figure that the plaintiffs came up with and put in their proposed injunction was something never mentioned at trial, never put in the pretrial order, and seemed to be kind of picked out of the air.

And I think, really, there's a broader issue here as to whether the terms of the injunction would shut down CellPro. And it goes beyond the $2,000 per item. And I would think if we're going to go any farther with this, there probably ought to be a hearing on the economic impact. And you cannot really talk about that until you know what the scope of the injunction is going to be.

MR. WARE: Well, our view is that that hearing was today, and we are not inclined to continue this indefinitely. We've made a suggestion to the Court. They've had their chance to respond to it. We

Page 90

hope that the Court will take our views into consideration and we're anxious to have the Court resolve the issue.

THE COURT: Well, back to the question, if you all are going to submit a paper on Simpson, then they can respond.

If you are not going to submit something, then I will just let the record sit the way it is, unless somebody tries to lob something in.

MR. WARE: Then let me say this: I think that Dr. Hausman's affidavit adequately sets out our points, if I can add one more simply, which is that as we looked at their all calculations today, this morning, what we saw is that when they calculated the per-unit costs of the disposables, they did it based on sales, or based on manufacturing something like 4600 units.

They actually sold and compared it to about 2300 units. So they figured out the cost of making and building an inventory for twice the number of product that they actually sold and then they said that that is the per-unit cost that should be considered.

So that's one point we wanted to add to what we said before. But, unless I'm mistaken, I'll speak with Mr. Ellis. I think probably we were going to underscore points that are in Dr. Hausman's affidavit and it's

Page 91

probably not necessary to go into it further.

THE COURT: Well, actually, what I was also going to say is it may not be something that anybody wants to hear. I see the injunction as an equitable remedy and a remedy where I have to try to get it right. And if somebody shows me today, next year, two years from now that it's not right, I may have to keep tinkering with it and until I do it.

And if it means I enter an injunction that misses the target a little bit and I go back and re-do it later, I'll go back and re-do it later. And I may appoint somebody to go back out and give me some accurate numbers and have them do it.

But we'll see.

MR. WARE: Thank you very much, your Honor.

THE COURT: All right. I think what's going to happen is the next thing I will see is a motion for summary judgment on patent misuse and I will get working on issues on my plate, including enhance -- enhancement of damages, attorneys' fees and nature of the injunction.

And when I receive the briefing on misuse, I take it one of the things I'll see is whether there needs to be evidentiary discovery on this subject or whether I can resolve it without further discovery.

(Counsel respond "Thank you, your Honor.")

Page 92

(Court recessed at 12:37 p.m.)

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